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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,723	12/27/2001	Rajiv Shah	047711-0288	7474

7590 12/29/2005

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EXAMINER
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NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/033,723

Applicant(s)

SHAH ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 May 0103 and 09 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28,30 and 32-78 is/are pending in the application.
- 4a) Of the above claim(s) 46-66,68 and 69 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28,30,35,38,41-45,71-73,77 and 78 is/are allowed.
- 6) ☒ Claim(s) 32-34, 36, 37, 39, 40, 67, 70 and 74-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for  
5 continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/3/05 has been entered.

An amendment of 10/3/05 amended claims 28, 32 and 35, and added  
10 new claims 70-78. A supplemental amendment of 11/9/05 amended claims 28, 32 and 71.

Claims in the application are 28, 30 and 32-78.

Claims 46-66, 68 and 69 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a  
15 nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/19/05.

Claims examined on the merits are 28, 30, 32-45, 67 and 70-78.

The text of those sections of Title 35, U.S. Code not included in  
20 this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.  
112:

25 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-34, 36, 37, 39, 40 and 70 are rejected under 35

5 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed  
10 invention.

When requiring the active protein to be molded in a recess in a block and hardened prior to being disposed within the space of a sensor body as now required by amended claim 32, the specification supports only an invention requiring the active protein in solidified  
15 form to be sufficiently immobilized to minimize swelling and shrinkage as now required by amended claims 28 and 71. If the swelling and shrinkage are not minimized as in claims 28 and 71, molding in the recess of a block of a mold as now required in claim 32 will not function as disclosed in the specification. It is suggested that  
20 claim 32 be amended as claims 28 and 71 to require sufficient immobilization to minimize swelling that would deform shape of the sensor body and shrinkage the would create voids between the active protein in solidified form and the sensor body.

Where the specification recites the shapes of claim 70 is not  
25 readily apparent. The page and line where these shapes are recited should be pointed out.

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***Claim Rejections - 35 USC § 112***

Claims 67, 74-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 is confusing by requiring a pellet to be sufficiently hard to maintain shape with external forces since claim 28 as now amended on which claim 67 depends now requires such hardness to be inherent. It is suggested that "that is hard enough to maintain its shape without external forces" be deleted from claim 67.

Where recited in claims 74-76, "a recess", "a block" and/or "a mold" is confusing and unclear since claim 71 requires a recess, block and mold. Therefore, claims dependent on claim 71 should recite "the recess", "the block" and/or "the mold".

***Conclusion***

Claims 28, 30, 35, 38, 41-45, 71-73, 77 and 78 are allowable.

Claims 32-34, 36, 37, 39, 40, 67, 70 and 74-76 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-

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0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR)

5 system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see [http://pair-](http://pair-direct.uspto.gov)

10 direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN

15 12/27/05